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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,211	02/12/2004	Silvia Burvenich	1522-1003-1	4018

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EXAMINER	
THOMAS, DAVID C	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,211	BURVENICH ET AL.	
	Examiner	Art Unit	
	David C. Thomas	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, drawn to methods of identifying a person with or at risk for developing Parkinson's disease, classified in class 435, subclass 6.

II. Claims 7-10, drawn to a kit comprising oligonucleotides and restriction enzymes, classified in class 536, subclass 24.31 and class 435, subclass 183.

III. Claims 11, 20, 21, 31, and 32, drawn to methods of prevention or treatment of Parkinson's disease or screening for compounds that interfere with ADH1C expression, classified in class 424, subclass 93.1 and class 514, subclasses 2 and 44.

IV. Claims 12, 17-19 and 22-30, drawn to a pharmaceutical composition for treatment or prevention of Parkinson's disease comprising a human ADH1C gene, classified in class 424, subclass 93.1 and class 514, subclasses 44 and 2-21.

V. Claims 13-16, drawn to a transgenic, non-human animal comprising a human ADH1C gene, classified in class 800, subclass 8.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the kit comprising oligonucleotides and restriction enzymes of group II can be used in various nucleic acid diagnostic applications such as Southern blotting, detection of amplification products, or primer extension assays, as well as the process of group I.

Searching the inventions of Groups I and II together would impose serious search burden. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for a kit comprising oligonucleotides and restriction enzymes of Group II and methods of identifying a person with or at risk for developing Parkinson's disease of Group I is not coextensive.

4. Inventions I and III, I and IV, and I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these inventions would be used together. The method of identifying a person with or at risk for developing Parkinson's disease (group I) and the method of prevention or treatment of Parkinson's disease or screening for compounds that interfere with ADH1C expression (group III), are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. The pharmaceutical composition for treatment or prevention of Parkinson's disease comprising a human ADH1C gene (group IV) and a transgenic, non-human animal

comprising a human ADH1C gene (group V) are also unrelated to the method of identifying a person with or at risk for developing Parkinson's disease (group I) as they comprise distinct steps and utilize different products which demonstrates that each has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Therefore, each invention is divergent in materials and steps. For these reasons the Inventions I and III, I and IV, and I and V are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I and II, I and IV, and I and V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I and II, I and IV, and I and V together.

5. Inventions II and III, II and IV, and II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these inventions would be used together. A kit comprising oligonucleotides and restriction enzymes (group II) and the method of prevention or treatment of Parkinson's disease or screening for compounds that interfere with ADH1C expression (group III), are unrelated as they comprise distinct steps and utilize different products which demonstrates that each has a different mode of operation. The pharmaceutical composition for treatment or prevention of Parkinson's disease comprising a human ADH1C gene (group IV) and a transgenic, non-human animal comprising a human

ADH1C gene (group V) are also unrelated to a kit comprising oligonucleotides and restriction enzymes (group II) as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Therefore, each invention is divergent in materials and steps. For these reasons the Inventions II and III, II and IV, and II and V are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups II and III, II and IV, and II and V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups II and III, II and IV, and II and V together.

6. Inventions III and IV, are related as product and process of use. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different product, or (2) the product as claimed can be used to practice another and materially different process of using that product. (MPEP § 806.05(h)). In this case, a pharmaceutical composition such as a protein or nucleic acid for treatment or prevention of Parkinson's disease comprising a human ADH1C gene (Group IV) can be used in a diagnostic application or to produce antibodies as opposed to its use in a method of treating a pathology.

Searching the inventions of Groups III and IV together would impose serious search burden. The inventions of Groups III and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the

search for a pharmaceutical composition for treatment or prevention of Parkinson's disease comprising a human ADH1C gene (Group IV) and the methods of prevention or treatment of Parkinson's disease or screening for compounds that interfere with ADH1C expression (Group III) is not coextensive.

7. Inventions III and V, are related as product and process of use. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different product, or (2) the product as claimed can be used to practice another and materially different process of using that product. (MPEP § 806.05(h)). In this case, methods of prevention or treatment of Parkinson's disease or screening for compounds that interfere with ADH1C expression (Group III) can be practiced in human subjects during clinical trials as well as in a transgenic, non-human animal comprising a human ADH1C gene (Group V).

Searching the inventions of Groups III and V together would impose serious search burden. The inventions of Groups III and V have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for a transgenic, non-human animal comprising a human ADH1C gene (Group V) and the methods of prevention or treatment of Parkinson's disease or screening for compounds that interfere with ADH1C expression (Group III) is not coextensive.

8. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these products would be used together.

A pharmaceutical composition for treatment or prevention of Parkinson's disease comprising a human ADH1C gene (Group IV) and a transgenic, non-human animal comprising a human ADH1C gene (Group V), are unrelated as they comprise or utilize different products which demonstrates that each product has a different mode of operation and different functions. Each invention performs this function using a structurally and functionally divergent material. For these reasons the Inventions IV and V are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups IV and V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups IV and V together.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Thomas whose telephone number is 571-272-3320. The examiner can normally be reached on 5 days, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David C. Thomas 8/25/06
Patent Examiner
Art Unit 1637

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